



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,964	07/13/2006	Chudi Guan	NEB-236-PUS	7911
28986	7590	05/03/2010		
HARRIET M. STRIMPEL, D. Phil. New England Biolabs, Inc. 240 COUNTY ROAD IPSWICH, MA 01938-2723				
EXAMINER				
RAMIREZ, DELIA M				
ART UNIT		PAPER NUMBER		
1652				
NOTIFICATION DATE		DELIVERY MODE		
05/03/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

STRIMPEL@NEB.COM

Goldberg@neb.com

weremuth@neb.com

ADVISORY ACTION

1. Claims 18-23, 25, 29-30, 32-47 are pending.
2. The request for entering amendments to claims 32, 36, 38, 40, 42-43, cancellation of claims 33-35, and arguments filed on 4/16/2010 under 37 CFR 1.116 in reply to the Final Action mailed on 10/19/2009 are acknowledged. The proposed amendments to the claims will not be entered. While amendments to the claims seem to overcome the objections made to claims 36, 38 and 42, the proposed amendments to the claims raise new issues which would require further consideration and do not overcome the previous rejections as discussed below.
3. Proposed amended claim 32 (and dependent claims 36-47) would be rejected as being indefinite due to the recitation of "a modified T-odd phage endonuclease having two naturally occurring catalytic domains separated by a β -bridge differing by a deletion....of one of more amino acids in the β -bridge from the sequence at 44-49 in SEQ ID NO: 12 so as to cause altered activity of the endonuclease" for the following reasons. First, it is unclear as to what a T-odd phage is. In addition, as written it is unclear as to what is differing in the endonuclease: (1) the two catalytic domains differing from each other, or (2) the β -bridge of the modified endonuclease from the β -bridge of the polypeptide of SEQ ID NO: 12, wherein the β -bridge of the polypeptide of SEQ ID NO: 12 is the peptide of amino acids 44-49 of SEQ ID NO: 12. Moreover, the term "to cause altered activity of the endonuclease" is unclear and confusing in the absence of a reference point, i.e., altered activity with respect to what.
4. Proposed amended claim 40 would be rejected as being indefinite due to the recitation of "the composition according to claim 32 wherein the modified recombinant phage-odd endonuclease is selected from..." for the following reasons. First, it is unclear as to what a phage-odd endonuclease is. Second, the claim is broader in scope than claim 32, thus not further limiting. Assuming that the term T-odd phage represents any type of T phage, the listed endonucleases are not all from T phages. Third, as written, it appears as if claim 40 is stating that every one of the endonucleases recited in the group (e.g.,

Art Unit: 1652

Y. pestis phage phiA1122 endonuclease) is an endonuclease which has the modifications recited in claim 32 due to the recitation of "wherein the modified ...endonuclease is selected from... *Y. pestis* phage phiA1122 endonuclease". However, the specification appears to refer to the endonucleases in the list as wild-type endonucleases.

5. Proposed amended claim 32 and dependent claims 36-39, 41-47 would be rejected under 35 USC 112, first paragraph, as containing new matter. Specifically, there is no support for the genus of "T-odd phage endonucleases" recited in the claims.

6. Proposed amended claim 32 and dependent claims 36-47 would remain rejected under 35 USC 112 first paragraph, as lacking adequate written description and not being fully enabled for the reasons of record. It should also be noted that even if (1) support were to be found for the recited "T-odd phage endonucleases", and (2) one were to interpret the term "T-odd phage" as any phage which is labeled with the letter T next to an odd number, there is no limit as to the types of phages encompassed by that term since it will encompass phages labeled T3, T5, T7,..... and T_{2N-1} where N can be any integer. Neither the specification nor the art provide any teaching or guidance as to the structure of any endonuclease which can be isolated from any T_{2N-1} phage. Therefore, such genus of endonucleases is not adequately described or fully enabled.

7. The proposed amended claims would remain rejected under 35 USC 102(b) and 103(a) as indicated in the Final action of 10/19/2009 since the endonuclease of Beck et al. meets the structural limitations recited in the proposed amended claims. It is reiterated herein that limitations such as recombinant or modified are simply product-by-process limitations which are not given patentable weight since the patentability of a product is determined solely on its structural/functional characteristics.

8. For purposes of Appeal, the status of the claims is as follows:

Claim(s) allowed: NONE

Claims(s) objected to:

Art Unit: 1652

Claim(s) rejected: 32-47

Claim(s) withdrawn from consideration: 18-23, 25, 29-30

9. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (571) 273-8300. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez, Ph.D., whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on (571) 272-0811. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

/Delia M. Ramirez/

Primary Examiner
Art Unit 1652

DR
April 30, 2010